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| 10/528,842 | 07/26/2005 | Gallus Schechner | P2107-267 | 8538 |
| 2352 7590 02/17/2010 OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403 | | | | |
| EXAMINER | | | | |
| DEES, NIKKI H | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,842

Applicant(s)

SCHECHNER ET AL.

Examiner

Nikki H. Dees

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-32,34,35 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-32,34,35 and 37-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed October 20, 2009, has been entered. Claims 1, 3-5, 7-32, 34, 35, and 37-42 are currently pending in the Application. Claim 33 has been cancelled. The previous objections to claims 7, 21, 22, 25-28, 30, 31, 35, and 42 have been withdrawn in view of the amendments to these claims. The previous 112 rejection of claim 24 has been withdrawn in view of the amendment to claim 24. The previous objection to and rejection of claim 33 have been withdrawn in view of the cancellation of claim 33.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-5, 7-32, 34, 35 and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kropf et al. (DE 10063945 A1) in view of Greenberg et al. (5,980,955).

4. Kropf et al. teach a dental adhesive film comprising a poorly soluble calcium salt [0009]. The slightly water soluble calcium salts are preferably salts of hydroxyapatite or fluoroapatite [0015]. The calcium salts are preferably from 10-300 nm in size, and are

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in the form of rod-shaped crystals [0015]. The film produced comprises about 1% of the composite material of the invention [0089]. The calcium salt is preferably provided in combination with a protein. Proteins may include casein, collagen, albumin and gelatin [0019], [0026]. The proteins may also function as surface-modification agents by adsorbing to the nanoparticles of calcium and preventing agglomeration of the particles [0018].

5. Kropf et al. go on to teach sweeteners for use in their invention including sucrose, lactose, fructose [0054]. They also teach intense sweeteners such as aspartame, thaumatin and sodium cyclamate [0054], inclusion of which would result in a substantially sugar-free product.

6. The invention of Kropf et al. may further comprise fluorine compounds such as sodium fluoride or tin fluoride [0047]. The invention may also comprise flavors and other fillers [0049]-[0055].

7. Kropf et al. teach chewing gums as another means of introducing active ingredients to tooth and gum surfaces [0003].

8. Kropf et al. are silent as to the composition of the particular coating layers of the chewing gum. They are also silent as to a method for making a chewing gum product comprising their calcium composite.

9. Greenberg et al. teach a coated chewing gum product wherein the coating contains a poorly water-soluble salt of calcium (Abstract).

10. The coating material of Greenberg et al. may further comprise sweeteners such as dextrose, maltose, erythritol, xylitol, hydrogenated isomaltulose (isomalt) and other

polyols alone or in combination. High intensity sweeteners are also taught for use in the invention (col. 5 lines 61-62). Further, there may be layers of different primary coating materials (col. 4 lines 21-32).

11. Greenberg et al. state that each component of the coating may be applied in a single layer, or in a plurality of layers that are the same or different. Preferably, about 30 to 60 layers are applied (col. 7 lines 4-13).

12. Greenberg et al. also teach a method for producing a chewing gum comprising coating a gum core with a coating syrup comprising a slightly water-soluble calcium salt (Abstract). The coating syrup may further comprise sweeteners (col. 5 lines 40-56). The chewing gum core is coated by at least one coating step. Preferably, about 30 to 60 layers are applied (col. 7 lines 4-13). After coating, the core is dried (col. 7 lines 28-36). The gum core may also be coated with a dry powder of sweetener after coating with a liquid syrup (col. 6 lines 63-66). The powder may also comprise calcium carbonate (col. 7 lines 1-3). The calcium salt is taught in an amount preferably from 1.5 to about 5% in the coating layer (col. 2 lines 64-67).

13. As Kropf teaches the composite of a protein and nanoparticle calcium salt for the remineralization of tooth enamel, as well of the use chewing gums to expose remineralizing agents to teeth, one of ordinary skill would have found it obvious to include the remineralizing agents of Kropf in traditional chewing gum compositions, as taught by Greenberg, in order to result in a chewing gum product containing nanoparticle-sized calcium in a form that has significant residence time in the mouth in

order to improve the dental hygiene of the user, or mineralize the enamel or dentine of the user in the presence of the calcium particles.

Response to Arguments

14. Applicant's arguments filed October 20, 2009, have been fully considered but they are not persuasive.

15. Applicant argues (Remarks, pp. 10-11) Kropf is silent to the use of the presently claimed calcium salts in combination with proteins in a chewing gum product.

16. Kropf is used to teach a composite of a slightly water-soluble calcium salt and a protein component, with the salts and proteins taught by Kropf being the same as those claimed by Applicants. Further, the particle size and the shape of the calcium salt as claimed by Applicants are the same as taught by Kropf. The composition of Kropf is used for remineralization of dentin.

17. Kropf further teaches that chewing gums may be used to administer agents to the surface of the tooth as they generally have a long residence time in the mouth [0002]. Again, as Kropf teaches the precise combination of calcium salt and protein as claimed by Applicant, and Kropf teaches that chewing gums are an effective vehicle for administering agents to the surface of the tooth, the Examiner maintains that one of ordinary skill reading the teachings of Kropf would have indeed been motivated to provide the composite of Kropf in a chewing gum form.

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18. Applicant argues (Remarks, p. 12) that the calcium salts of Kropf would not be suitable for use in chewing gum coatings due to the low solubility of the salts and the tendency of the salts to recrystallize.

19. It is noted that chewing gum coatings may be applied as “wet” and “dry” coatings. The “wet” coatings are commonly a syrup containing a high percentage dry matter of the coating material, while the “dry” coating is a powdered form of the coating material. When applied “wet”, the coating is then dried to evaporate the moisture in the syrup, providing the chewing gum core with a hard outer coating. Alternatively, a “wet” coating may be followed by a “dry” coating, with the “dry” coating often consisting primarily of the same material as the “wet” coating, absent the moisture. As the coatings are intended to be dry in their final form, the low solubility of the calcium salts, and the tendency of the salts to crystallize, would not have precluded their use in the coatings. Indeed, the composite salt need only to be well mixed, not completely soluble, in the coating syrup in order to be evenly distributed on the gum core.

20. Applicant argues that the failure of Kropf to detail the inclusion of their calcium composite in a chewing gum indicates that a chewing gum would not have been a suitable form for delivery of the composite (Remarks, pp. 13-14).

21. There is no teaching away by Kropf from the use of the composite in a chewing gum. The fact that Kropf does not specifically detail the use of the composite in a chewing is not an indication that such an inclusion is not obvious. Rather, the suggestion that chewing gums are an effective means for delivering agents to the

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surface of teeth provides motivation for one of ordinary skill to incorporate the agents of Kropf in a chewing gum form, thus allowing for more extensive contact of the composite with the teeth than would have been provided by the targeted use of the dental adhesive film of Kropf.

22. Kropf is not used to teach the method of preparation of the chewing gum comprising the calcium salt. Regarding the method of use of the instant invention being different than Kropf, as Kropf clearly teaches the inclusion of remineralizing agents in chewing gums, one of ordinary skill would have considered it obvious to provide said agents in gum, with the intent that the gums be chewed to deliver the agents to the surface of the teeth.

Conclusion

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-4:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H. D./
/Lien T Tran/
Primary Examiner, Art Unit 1794

Nikki H. Dees
Examiner
Art Unit 1794